K111405
Pg. 1 of 4

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BEVER
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510(k) Summary

Date of summary: December 30, 2011

1. Submitter (Owner) of 510 (k):

Hangzhou Bever Medical Devices Co., Ltd.
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2. Contact person:

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3. Device Name:

Common Name: Intermittent Urethral Catheter
Trade Name: BEVER™ Intermittent Catheter
Classification name: Urological catheter and accessories (21 CFR 876.5130, Product Code GBM)

4. Predicate Device:

BEVER is claiming substantial equivalence to the following medical devices:
Rüsch Intermittent Urethral Catheters – K033023
Astra Tech AB LoFric® Primo™ Single Use Urinary Catheter – K050874

5. Device Description

BEVERTM Intermittent Catheter is sterile, single use device to be designed as an intermittent pathway for drainage of the bladder. It is available for men, women and children, in uncoated and coated variants and in two different tip configurations of Nelaton (straight and rounded) and Tiemann (curved and tapered) respectively. There are two polished drainage eyelets on the catheter in various configurations and types.

The uncoated catheter consists of a tubular polyvinyl chloride catheter shaft with attached a drainage funnel. The catheter is available in sizes 6Fr ~ 22Fr in 2Fr increments for Nelaton-tip and sizes 8Fr ~ 22Fr in 2Fr increments for Tiemann-tip.

The coated catheter consists of a tubular polyvinyl chloride catheter shaft, coated with a hydrophilic low-friction coating, with attached a drainage funnel, and a sterile water packet is placed in the package. The surface of coated catheter is hydrophilic and when the coated catheter is activated with the sterile water in the attached water

packet, it becomes slippery and thus reduces friction against the urethra. This allows the coated catheter to slide in and out of the urethra in the most comfortable way. And, just as importantly, there's less risk of long-term complications from the repeated friction of self-catheterizing. The coated catheter is available in sizes 6Fr ~ 22Fr in 2Fr increments for Nelaton-tip and sizes 8Fr ~ 22Fr in 2Fr increments for Tiemann-tip.

6. Indications for Use

The BEVER™ Intermittent Catheter is indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder - voiding episode. The catheter is inserted into urethra to reach the bladder allowing urine to drain.

7. Substantial Equivalence

The BEVER™ Intermittent Catheter maintains the same intended use as the predicate devices. It is a device that is inserted through the urethra and used to drain urine from the bladder.

The BEVER™ Intermittent Catheter is composed essentially of the same materials as the predicate devices. The material for both devices is PVC and PVP for coating.

The BEVER™ Intermittent Catheter has the same design and performance characteristic as the predicate devices.

8. Device Performance

The dimension, design, material, sterility, packaging and labeling of BEVER™ Intermittent Catheter are conformed with EN 1616:1997.

According to the device performance testing protocol, the device is compliance with EN 1616:1997, EN 1618:1997.

9. Summary of Testing

9.1 Biocompatibility testing was performed based on ISO 10993 requirements

The indwell time of BEVER™ Intermittent Catheter is about 1-3 minutes. And it contact mucosal membrane. According to 510(k) Memorandum - #G95-1 Table 1 Initial Evaluation Tests for Consideration, the biocompatibility testing show consider the following 3 items:

- Cytotoxicity
- Sensitization
- Irritation

a) Test for in vitro cytotoxicity (MTT cytotoxicity test)

An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article, Intermittent Catheter, based on the International Organization for Standardization ISO 10993-5:2009: Biological evaluation of medical devices-Part 5:Tests for in vitro cytotoxicity; ISO 10993-12:2007: Biological evaluation of medical devices-Part 12: Sample preparation and reference materials.

Four concentrations (100%, 75%, and 25%) of the test article extracts, the blank control, 100% of the negative control and the positive control were prepared using Minimum Essential Medium (MEM) supplemented with 10% calf serum. The semi-confluent monolayers of L-929 mouse fibroblast cells were incubated with the test extract and other three controls, supplemented with 10% calf serum in a 96-well microplate respectively at 37°C under the condition of 5% CO_2.. At 24h, the MTT colorimetric assay was employed and plate was read on a microplate reader at 570 and 650nm. The viability of the cells was calculated.

Under the conditions of this study, the viability of 100% extract of the test article was 86%, it had not a cytotoxic potential.

b) Test for irritation (vaginal irritation test)

The purpose of the study was to evaluate the potential irritation response of the extract of the test article, Intermittent Catheter contact with vaginal tissue. This study was conducted based on the requirements for the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; ISO 10993-12:2007: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test extract were contacted with vaginal tissue 1 time (once a day) directly for five consecutive days. At 24h after the final treatment, the tissues were examined macro- scopically and microscopically. The irritant effects on vaginal tissue were evaluated and scored.

Under the conditions of this study, the macroscopic reaction of test extract was relatively similar to that of the reagent control. Microscopically, the extract of the test article was classified as a non- irritant as compared to the control.

c) Test for skin sensitization (Maximization test)

A guinea pig maximization test of the test article, Intermittent Catheter, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; ISO 10993-12:2007: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride solution (SC) and cotton seed oil (CSO). Each extract was injected intradermally and patched occlusively to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched occlusively to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals were received a challenge patch of the appropriated test article extract and the reagent control. All sites were scored at 24h and 48h after patch removal.

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

9.2 Packaging Shipment Testing was performed based on ISTA Procedure 2A

2 pieces of packaged-products were submitted for the packaging shipment testing in accordance with ISTA Procedure 2A. After all tests completed, no tearing was observed on the inner packaging and outer packaging.

10. sterility and shelf life

The device is sterilized by EO. The water packet in coated Intermittent Catheter is sterilized by radiation. The sterilization process is compliance with ISO11135-1: 2007, ISO11137-1: 2006, ISO11137-2: 2006, ISO11137-3: 2006.

Regarding the accelerated aging testing result, after 137 days accelerated aging, BEVER™ coated Intermittent Catheter is still compliance the requirements of device specification. The shelf life of BEVER™ coated Intermittent Catheter could be considered as 3 years. And, according to the real time stability study, the 3 years shelf life of BEVER™ Coated Intermittent Catheter has been validated. Herewith we declare that the shelf life of BEVER™ Coated Intermittent Catheter is 3 years.

Regarding the accelerated aging testing result, after 183 days accelerated aging, BEVER™ uncoated Intermittent Catheter is still compliance the requirements of device specification. The shelf life of BEVER™ Uncoated Intermittent Catheter could be considered as 4 years. And, according to the real time stability study, the 4 years shelf life of BEVER™ Coated Intermittent Catheter has been validated. Herewith we declare that the shelf life of BEVER™ Coated Intermittent Catheter is 4 years.

11. Conclusions

These proposed devices have the same intended use and technological characteristics to the currently-marketed predicate devices. No new issues of safety or effectiveness are introduced by using these devices. Therefore we believe the proposed devices are substantially equivalent to the currently-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Management Representative
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HANGZHOU ZHEJIANG 311121
CHINA

FEB 13 2012

Re: K111405
Trade/Device Name: BEVER™ Intermittent Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: May 16, 2011
Received: January 11, 2012

Dear Ms. Zhou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):
Device Name: BEVER™ Intermittent Catheter
Indications For Use:

The BEVER™ intermittent catheter is indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder -voiding episode. The catheter is inserted into urethra to reach the bladder allowing urine to drain.

Prescription Use Yes AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111405